

EXPEDITED PROCEDURE EXAMINING GROUP: 3767

Docket: 33333/US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Roney Graf	
Appln. No.:	10/621,970	
Filing Date:	July 17, 2003	Examiner: Mark Han
Title:	Administering Apparatus Comprising a Dosage Display	Group Art Unit: 3767

**AMENDMENT AFTER FINAL
(UNDER 37 CFR 1.116)**

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

In response to the Final Office Action of September 12, 2006, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 14 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently amended) An administering apparatus with a dosage display, comprising:
 - a) a casing comprising a front casing section and a rear casing section, and a reservoir for a fluid product, wherein the front casing section and the rear casing section are plugged into each other along a common central longitudinal axis, in a non-releasable connection, whereby the front casing section and the rear casing section cannot be moved relative to each other, either axially or rotationally about the longitudinal axis;
 - b) a driven device which acts on said product contained in said reservoir, in order to deliver product;
 - c) a dosing means, using which a product dosage to be delivered can be selected, and which comprises a dosage scale with a number of dosage marks axially spaced out from each other; and
 - d) a drive device coupled to said driven device for driving the driven device, said drive device performing a delivery stroke from an initial position, in a drive direction, up to a delivery stopper, the length of said delivery stroke counter to the drive direction being limited by selecting the product dosage by means of said dosing means;
 - e) wherein said casing is transparent, at least in an area overlapping said dosage scale; and wherein
 - f) the drive device carries an indicator marking, in order to indicate the initial position of the drive device through the transparent area of the casing, relative to said dosage marks.
2. (Original) The administering apparatus as set forth in claim 1, wherein the dosing means comprises another indicator, in order to display the product dosage selected on the dosage scale or on another dosage scale.
3. (Previously presented) An administering apparatus with a dosage display, comprising:
 - a) a casing comprising a reservoir for a fluid product;

- b) a driven device which acts on said product contained in said reservoir, in order to deliver product;
- c) a dosing means, using which a product dosage to be delivered can be selected, and which comprises a dosage scale with a number of dosage marks axially spaced out from each other; and
- d) a drive device coupled to said driven device for driving the driven device, said drive device performing a delivery stroke from an initial position, in a drive direction, up to a delivery stopper, the length of said delivery stroke counter to the drive direction being limited by selecting the product dosage by means of said dosing means;
- e) wherein said casing is transparent, at least in an area overlapping said dosage scale;
- f) wherein the drive device carries an indicator marking, in order to indicate the initial position of the drive device through the transparent area of the casing, relative to said dosage marks;
- g) wherein the dosing means comprises another indicator, in order to display the product dosage selected on the dosage scale or on another dosage scale; and wherein
- h) said indicator marking of the drive device and said other indicator overlap in the initial position of the drive device, if the drive device can perform the maximum stroke, set by selecting the product dosage, from the initial position.

4. (Original) The administering apparatus as set forth in claim 1, wherein the dosing means comprises a dosing member which performs a dosing movement relative to the casing, in order to select the product dosage to be delivered, and wherein the position of said dosing member is displayed on the dosage scale or on another dosage scale.

5. (Original) The administering apparatus as set forth in claim 4, wherein the dosing member is coupled to the casing such that it can be rotated about a rotational axis pointing in the drive direction.

6. (Previously presented) An administering apparatus with a dosage display, comprising:
a) a casing comprising a reservoir for a fluid product;

- b) a driven device which acts on said product contained in said reservoir, in order to deliver product;
- c) a dosing means, using which a product dosage to be delivered can be selected, and which comprises a dosage scale with a number of dosage marks axially spaced out from each other; and
- d) a drive device coupled to said driven device for driving the driven device, said drive device performing a delivery stroke from an initial position, in a drive direction, up to a delivery stopper, the length of said delivery stroke counter to the drive direction being limited by selecting the product dosage by means of said dosing means;
- e) wherein said casing is transparent, at least in an area overlapping said dosage scale;
- f) wherein the drive device carries an indicator marking, in order to indicate the initial position of the drive device through the transparent area of the casing, relative to said dosage marks;
- g) wherein the dosing means comprises a dosing member which performs a dosing movement relative to the casing, in order to select the product dosage to be delivered, and wherein the position of said dosing member is displayed on the dosage scale or on another dosage scale; and wherein
- h) the dosing member and the casing are coupled via a swivel joint, such that a rotational movement of the dosing member about a rotational axis pointing in the drive direction causes an axial translational movement of the dosing member.

7. (Previously presented) An administering apparatus with a dosage display, comprising:

- a) a casing comprising a reservoir for a fluid product;
- b) a driven device which acts on said product contained in said reservoir, in order to deliver product;
- c) a dosing means, using which a product dosage to be delivered can be selected, and which comprises a dosage scale with a number of dosage marks axially spaced out from each other; and
- d) a drive device coupled to said driven device for driving the driven device, said drive device performing a delivery stroke from an initial position, in a drive direction, up to a

delivery stopper, the length of said delivery stroke counter to the drive direction being limited by selecting the product dosage by means of said dosing means;

e) wherein said casing is transparent, at least in an area overlapping said dosage scale;

f) wherein the drive device carries an indicator marking, in order to indicate the initial position of the drive device through the transparent area of the casing, relative to said dosage marks; and wherein

g) the dosing means comprises a dosing member comprising an inner dosing body and an outer dosing body, between which a gap is formed into which the casing protrudes, wherein said inner dosing body forms a dosing stopper for selecting the product dosage, wherein said dosing stopper can be adjusted in or counter to the drive direction by operating said outer dosing body.

8. (Previously presented) An administering apparatus with a dosage display, comprising:

a) a casing comprising a reservoir for a fluid product;

b) a driven device which acts on said product contained in said reservoir, in order to deliver product;

c) a dosing means, using which a product dosage to be delivered can be selected, and which comprises a dosage scale with a number of dosage marks axially spaced out from each other; and

d) a drive device coupled to said driven device for driving the driven device, said drive device performing a delivery stroke from an initial position, in a drive direction, up to a delivery stopper, the length of said delivery stroke counter to the drive direction being limited by selecting the product dosage by means of said dosing means;

e) wherein said casing is transparent, at least in an area overlapping said dosage scale;

f) wherein the drive device carries an indicator marking, in order to indicate the initial position of the drive device through the transparent area of the casing, relative to said dosage marks; and wherein

g) the dosing means comprises a dosing member which forms a dosing stopper, can be moved counter to the drive direction up to the drive device, and is movably coupled to the

casing, in order to select the product dosage by adjusting said dosing stopper relative to the casing.

9. (Previously presented) An administering apparatus with a dosage display, comprising:

- a) a casing comprising a reservoir for a fluid product;
- b) a driven device which acts on said product contained in said reservoir, in order to deliver product;
- c) a dosing means, using which a product dosage to be delivered can be selected, and which comprises a dosage scale with a number of dosage marks axially spaced out from each other; and
- d) a drive device coupled to said driven device for driving the driven device, said drive device performing a delivery stroke from an initial position, in a drive direction, up to a delivery stopper, the length of said delivery stroke counter to the drive direction being limited by selecting the product dosage by means of said dosing means;
- e) wherein said casing is transparent, at least in an area overlapping said dosage scale;
- f) wherein the drive device carries an indicator marking, in order to indicate the initial position of the drive device through the transparent area of the casing, relative to said dosage marks; and wherein
- g) the driven device comprises a piston and a piston rod acting on said piston in the drive direction, in order to deliver product from the reservoir by axially moving the piston in the drive direction; the drive device can be moved counter to the drive direction up to an adjustable dosing stopper; and the piston rod is prevented from moving counter to the drive direction and is coupled to the drive device such that it is slaved by the drive device in the drive direction.

10. (Original) The administering apparatus as set forth in claim 1, wherein the dosage marks are also spaced out from each other in the circumferential direction, around an axis pointing in the drive direction.

11. (Original) The administering apparatus as set forth in claim 1, wherein the casing is a support for the dosage scale for displaying the initial position of the drive device.
12. (Original) The administering apparatus as set forth in claim 1, wherein the dosing means comprises a dosing member which performs a dosing movement relative to the casing, in order to select the product dosage to be delivered, and forms another indicator which displays the product dosage selected on the dosage scale or another dosage scale.
13. (Original) The administering apparatus as set forth in claim 1, wherein the dosage scale serving to display the initial position of the drive device comprises a clearly assigned dosage symbol for at least a part of the dosage marks, said dosage symbol representing a product dosage corresponding to the assigned dosage mark.
14. (Previously presented) The administering apparatus as set forth in claim 1, wherein the drive device comprises a marking line on an outer surface area facing the casing, said marking line extending perpendicular to the drive direction and forming the indicator marking of the drive device.
15. (Original) The administering apparatus as set forth in claim 1, wherein the dosage marks are formed by lines which extend perpendicular to the drive direction.
16. (Original) The administering apparatus as set forth in claim 1, wherein said administering apparatus is an injection apparatus comprising an injection cannula of at most 30 gauge, or an injection cannula having an outer diameter of at most 320 μm and an inner diameter not specified in ISO 9626, wherein the wall thickness is thinner than is specified in ISO 9626.
17. (Original) The administering apparatus as set forth in claim 16, wherein said injection cannula is 31 or 32 gauge.
18. (Currently amended) An administering apparatus with a dosage display, comprising a casing, a reservoir for a fluid product, a driven device which acts on the product, a dosing means

for selecting a product dosage to be delivered comprising a dosage scale comprising a number of dosage marks axially spaced from each other, and a drive device coupled to the driven device for driving the driven device, wherein the casing comprises a front casing section and a rear casing section, wherein the front casing section and the rear casing section are plugged into each other along a common central longitudinal axis, in a non-releasable connection, whereby the front casing section and the rear casing section cannot be moved relative to each other, either axially or rotationally about the longitudinal axis, wherein the casing is transparent at least in an area overlapping the dosage scale, and wherein the drive device carries an indicator marking indicating the initial position of the drive device and viewable through the transparent area of the casing.

19. (Previously presented) The administering apparatus as set forth in claim 18, wherein the drive device performs a delivery stroke in a drive direction and can only be moved relative to the driven device opposite the drive direction, by a path length which corresponds to a remaining dosage in the reservoir.

20. (Previously presented) The administering apparatus as set forth in claim 1, wherein said rear casing section is transparent.

21. (Previously presented) The administering apparatus as set forth in claim 1, wherein said reservoir for said product is a disposable module, and at least one of said front or rear casing sections is disposable.

22. (Currently amended) An administering apparatus with a dosage display, comprising:
a) a casing comprising a front casing section and a rear casing section, and a reservoir for a fluid product;
b) a driven device which acts on said product contained in said reservoir, in order to deliver product;
c) a dosing means, using which a product dosage to be delivered can be selected, and which comprises a dosage scale with a number of dosage marks axially spaced out from each other; and

- d) a drive device coupled to said driven device for driving the driven device, said drive device performing a delivery stroke from an initial position, in a drive direction, up to a delivery stopper, the length of said delivery stroke counter to the drive direction being limited by selecting the product dosage by means of said dosing means;
- e) wherein said casing is transparent, at least in an area overlapping said dosage scale;
- f) wherein the drive device carries an indicator marking, in order to indicate the initial position of the drive device through the transparent area of the casing, relative to said dosage marks;
- g) wherein the dosing means comprises another indicator, in order to display the product dosage selected on the dosage scale or on another dosage scale; and The administering apparatus as set forth in claim 2;
- h) wherein said indicator marking of the drive device and said other indicator overlap in the initial position of the drive device, if the drive device can perform the maximum stroke, set by selecting the product dosage, from the initial position.

23. (Currently amended) An administering apparatus with a dosage display, comprising:

- a) a casing comprising a front casing section and a rear casing section, and a reservoir for a fluid product;
- b) a driven device which acts on said product contained in said reservoir, in order to deliver product;
- c) a dosing means, using which a product dosage to be delivered can be selected, and which comprises a dosage scale with a number of dosage marks axially spaced out from each other; and
- d) a drive device coupled to said driven device for driving the driven device, said drive device performing a delivery stroke from an initial position, in a drive direction, up to a delivery stopper, the length of said delivery stroke counter to the drive direction being limited by selecting the product dosage by means of said dosing means;
- e) wherein said casing is transparent, at least in an area overlapping said dosage scale;

f) wherein the drive device carries an indicator marking, in order to indicate the initial position of the drive device through the transparent area of the casing, relative to said dosage marks;

g) wherein the dosing means comprises a dosing member which performs a dosing movement relative to the casing, in order to select the product dosage to be delivered, wherein the position of said dosing member is displayed on the dosage scale or on another dosage scale; and ~~The administering apparatus as set forth in claim 4,~~

h) wherein the dosing member and the casing are coupled via a swivel joint, such that a rotational movement of the dosing member about a rotational axis pointing in the drive direction causes an axial translational movement of the dosing member.

24. (Currently amended) An administering apparatus with a dosage display, comprising:

a) a casing comprising a front casing section and a rear casing section, and a reservoir for a fluid product;

b) a driven device which acts on said product contained in said reservoir, in order to deliver product;

c) a dosing means, using which a product dosage to be delivered can be selected, and which comprises a dosage scale with a number of dosage marks axially spaced out from each other; and

d) a drive device coupled to said driven device for driving the driven device, said drive device performing a delivery stroke from an initial position, in a drive direction, up to a delivery stopper, the length of said delivery stroke counter to the drive direction being limited by selecting the product dosage by means of said dosing means;

e) wherein said casing is transparent, at least in an area overlapping said dosage scale;

f) wherein the drive device carries an indicator marking, in order to indicate the initial position of the drive device through the transparent area of the casing, relative to said dosage marks; and ~~The administering apparatus as set forth in claim 1,~~

g) wherein the dosing means comprises a dosing member comprising an inner dosing body and an outer dosing body, between which a gap is formed into which the casing protrudes, wherein said inner dosing body forms a dosing stopper for selecting the product

dosage, wherein said dosing stopper can be adjusted in or counter to the drive direction by operating said outer dosing body.

25. (Currently amended) An administering apparatus with a dosage display, comprising:

- a) a casing comprising a front casing section and a rear casing section, and a reservoir for a fluid product;
- b) a driven device which acts on said product contained in said reservoir, in order to deliver product;
- c) a dosing means, using which a product dosage to be delivered can be selected, and which comprises a dosage scale with a number of dosage marks axially spaced out from each other; and
- d) a drive device coupled to said driven device for driving the driven device, said drive device performing a delivery stroke from an initial position, in a drive direction, up to a delivery stopper, the length of said delivery stroke counter to the drive direction being limited by selecting the product dosage by means of said dosing means;
- e) wherein said casing is transparent, at least in an area overlapping said dosage scale;
- f) wherein the drive device carries an indicator marking, in order to indicate the initial position of the drive device through the transparent area of the casing, relative to said dosage marks; and The administering apparatus as set forth in claim 1,
- g) wherein the dosing means comprises a dosing member which forms a dosing stopper, can be moved counter to the drive direction up to the drive device, and is movably coupled to the casing, in order to select the product dosage by adjusting said dosing stopper relative to the casing.

26. (Currently amended) An administering apparatus with a dosage display, comprising:

- a) a casing comprising a front casing section and a rear casing section, and a reservoir for a fluid product;
- b) a driven device which acts on said product contained in said reservoir, in order to deliver product;

c) a dosing means, using which a product dosage to be delivered can be selected, and which comprises a dosage scale with a number of dosage marks axially spaced out from each other; and

d) a drive device coupled to said driven device for driving the driven device, said drive device performing a delivery stroke from an initial position, in a drive direction, up to a delivery stopper, the length of said delivery stroke counter to the drive direction being limited by selecting the product dosage by means of said dosing means;

e) wherein said casing is transparent, at least in an area overlapping said dosage scale;

f) wherein the drive device carries an indicator marking, in order to indicate the initial position of the drive device through the transparent area of the casing, relative to said dosage marks; and The administering apparatus as set forth in claim 1,

h) wherein the driven device comprises a piston and a piston rod acting on said piston in the drive direction, in order to deliver product from the reservoir by axially moving the piston in the drive direction; the drive device can be moved counter to the drive direction up to an adjustable dosing stopper; and the piston rod is prevented from moving counter to the drive direction and is coupled to the drive device such that it is slaved by the drive device in the drive direction.

27. (Previously presented) The administering apparatus as set forth in claim 3, wherein said reservoir for said product is a disposable module, and a portion of said casing is disposable.

28. (Previously presented) The administering apparatus as set forth in claim 7, wherein the dosage marks are also spaced out from each other in the circumferential direction, around an axis pointing in the drive direction.

29. (Previously presented) The administering apparatus as set forth in claim 7, wherein the dosage scale serving to display the initial position of the drive device comprises a clearly assigned dosage symbol for at least a part of the dosage marks, said dosage symbol representing a product dosage corresponding to the assigned dosage mark.

30. (Previously presented) The administering apparatus as set forth in claim 7, wherein the drive device comprises a marking line on an outer surface area facing the casing, said marking line extending perpendicular to the drive direction and forming the indicator marking of the drive device.

31. (Previously presented) The administering apparatus as set forth in claim 7, wherein the dosage marks are formed by lines which extend perpendicular to the drive direction.

32. (Previously presented) The administering apparatus as set forth in claim 8, wherein said administering apparatus is an injection apparatus comprising an injection cannula of at most 30 gauge, or an injection cannula having an outer diameter of at most 320 μm and an inner diameter not specified in ISO 9626, wherein the wall thickness is thinner than is specified in ISO 9626.

33. (Previously presented) The administering apparatus as set forth in claim 32, wherein said injection cannula is 31 or 32 gauge.

34. (Previously presented) The administering apparatus as set forth in claim 9, wherein the casing is a support for the dosage scale for displaying the initial position of the drive device.

REMARKS

The present communication responds to the Final Office Action of September 12, 2006 in which the Examiner allowed claims 3, 6-9 and 27-34, rejected claims 1, 2, 4, 5 and 10-21, and objected to claims 22-26. Claims 1, 2, 4, 5 and 10-21 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent Application Publication 2003/0004467 (“Musick et al.”).

The allowance of claims 3, 6-9 and 27-34 is appreciated, as is the indication of allowable subject matter in claims 22-26, which have been rewritten in independent form.

Claims 1 and 18 have been amended, without acquiescing to the rejections, to help more clearly claim the invention. No new subject matter has been added to the claims. Support for amended claims 1 and 18 can be found in general throughout the specification and in particular, for example, at page 9, lines 15-20.

Reconsideration is requested.

Allowable Subject Matter

The Applicants thank the Examiner for allowing claims 3, 6-9 and 27-34.

Claims 22-26 were objected to as being dependent upon a rejected base claim, but the Examiner indicated they would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 22-26 have been rewritten in independent form and are, therefore, in condition for allowance.

Rejection under 35 U.S.C. § 102

Claims 1, 2, 4, 5 and 10-21 were rejected under 35 U.S.C. § 102(e) as anticipated by Musick et al.

Applicant respectfully traverses the § 102(e) rejection.

Amended claim 1 is directed to an administering apparatus with a dosage display, including a casing including a front casing section and a rear casing section, and a reservoir for a fluid product, wherein the front casing section and the rear casing section are plugged into each other along a common central longitudinal axis, in a non-releasable connection, whereby the front casing section and the rear casing section cannot be moved relative to each other, either axially or rotationally about the longitudinal axis, a driven device which acts on the product contained in the reservoir, in order to deliver product, a dosing means, using which a product dosage to be delivered can be selected, and which includes a dosage scale with a number of dosage marks axially spaced out from each other, and a drive device coupled to the driven device for driving the driven device, the drive device performing a delivery stroke from an initial position, in a drive direction, up to a delivery stopper, the length of the delivery stroke counter to the drive direction being limited by selecting the product dosage by means of the dosing means, wherein the casing is transparent, at least in an area overlapping the dosage scale; and wherein the drive device carries an indicator marking, in order to indicate the initial position of the drive device through the transparent area of the casing, relative to the dosage marks.

Amended claim 18 is directed to an administering apparatus with a dosage display, including a casing, a reservoir for a fluid product, a driven device which acts on the product, a dosing means for selecting a product dosage to be delivered including a dosage scale including a number of dosage marks axially spaced from each other, and a drive device coupled to the driven device for driving the driven device, wherein the casing includes a front casing section and a rear casing section, wherein the front casing section and the rear casing section are plugged into each other along a common central longitudinal axis, in a non-releasable connection, whereby the front casing section and the rear casing section cannot be moved relative to each other, either axially or rotationally about the longitudinal axis, wherein the casing is transparent at least in an area overlapping the dosage scale, and wherein the drive device carries an indicator marking indicating the initial position of the drive device and viewable through the transparent area of the casing.

Examiner has asserted on page 2 of the Office Action that Musick et al. "shows an administering apparatus with a dosage display having a casing with a front casing section 7, rear

casing section 6, reservoir 11, driven device 8, dosing means 3 and drive device 5.” To the contrary, Musick et al. actually discloses a driver for use with administering multiple doses of a compound contained in a cartridge including a base 7, containing an internal female thread 14 and an oblong plate extension which is used to apply thumb pressure to a plunger 3, attached to a dual-chambered cartridge 2, and further discloses a position selector 6, which also serves as a sleeve housing for the plunger 3 which extends through the position selector 6 and is attached to the proximal septum 8 of the dual-chambered cartridge 2. (See Musick et al. page 4, paragraph [0031].)

Musick et al. does not disclose a front casing section and a rear casing section, wherein the front casing section and the rear casing section are plugged into each other along a common central longitudinal axis, in a non-releasable connection, whereby the front casing section and the rear casing section *cannot be moved* relative to each other, either axially *or rotationally* about the longitudinal axis. Instead, Musick et al. discloses that “the threaded position selector (6) is externally threaded with a pitch identical to that of the base (7),” (Musick et al. page 4, paragraph [0031].) and that the “screw-driven plunger displacement is activated by clockwise rotation of the position selector as shown in FIG. 4.” (*Id.*, at page 3, paragraph [0026].) Therefore, position selector 6 is moved rotationally relative to the base 7 and Musick et al. fails to disclose each of the elements of amended claims 1 and 18.

For at least the preceding reasons, the rejection of claims 1 and 18 under 35 U.S.C. § 102(e) should be reconsidered and withdrawn. Of course, the right to demonstrate that Musick et al. is not prior art by date or otherwise is reserved.

Rejection of the Dependent Claims

Because claims 2, 4, 5 and 10-17 and 19-21 depend directly or indirectly from the independent claims and incorporate all the limitations of the corresponding independent claims, they are allowable for the same reasons and, further, in view of their additional recitations.

Conclusion

This paper generates a fees for additional claims. The Commissioner is hereby authorized to charge the necessary fees to Deposit Account No. 04-1420.

The Commissioner is also hereby authorized to charge any deficiencies and credit any overpayments associated with this paper to Deposit Account No. 04-1420.

This application now stands in allowable form, and reconsideration and allowance are requested.

Respectfully submitted,

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Date: December 7, 2006

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